agent, the ratio of said drug substance to said surface modifier is 1:1 to 5:1, the amount of said surface modifier is in the range from 0.2% w/w to 5.0% w/w, and said volume weighted mean particle size is not increased more than two-fold during and after terminal steam sterilization, and wherein said composition is substantially completely devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier and substantially devoid of surfactant additives which coagulate on steam sterilization.

23. (Amended) The composition of claim 21 or claim 22, wherein the suspension also includes a non-surfactant additive to adjust osmotic pressure.

25. (Amended) The composition of claim 22, wherein the polyhydroxy compound is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol, and mixtures thereof.

28. (Amended) The composition of claim 22, wherein the suspension also contains a pharmaceutical excipient for ophthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble drug substance.

Previous claims 33-37 have been renumbered as 32-36 below:

32. (Amended) The composition of claim 21, wherein the active substance is a sterol.

33. (Amended) The composition of claim 32, wherein the sterol is alfaxalone.

34. (Amended) A lyophilized or spray dried powder prepared from the composition of claim 22.

35. (Amended) A composition according to claim 22, wherein the water-insoluble or poorly water-soluble drug substance is suitable for either immediate release or sustained release delivery of said drug substance by parenteral administration.

36. (Amended) The composition of claim 35, wherein the parenteral administration is intramuscular, intravenous, or subcutaneous administration.

Add the following claims:

37. (New) The composition of claim 31, wherein the immunosuppressive agent is a cyclosporin.

38. (New) An aqueous suspension comprising particles of a water insoluble or poorly soluble biologically active substance, one or more surface modifiers, and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, sealed in a vial under nitrogen atmosphere, wherein the ratio of the active substance to the surface modifier and/or the thermoprotecting agent being selected so as to provide particle size stability during and after terminal steam sterilization, and the particle size subsequent to terminal steam sterilization is not more than about two-fold of the volume weighted mean particle size prior to the terminal steam sterilization.

39. (New) An aqueous suspension comprising particles of a water insoluble or poorly soluble biologically active substance, one or more surface modifiers, and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, sealed in a vial under nitrogen atmosphere, the ratio of the active substance to the surface modifier and/or the thermoprotecting agent being selected to provide particle size stability during and after terminal steam sterilization wherein the particle size subsequent to terminal steam sterilization is not more than about two-fold of the volume weighted mean particle size prior to the terminal steam sterilization, wherein the suspension is substantially devoid of surfactants that require elevation of their cloud point temperature by addition of a cloud point modifier for further stabilization.

40. (New) The suspension of claim 38, wherein the pH of the suspension before terminal steam sterilization is from about 5 to about 9.

41. (New) The suspension of claim 38, which also includes a non-surfactant additive to adjust osmotic pressure of the suspension.

42. (New) The suspension of claim 38, which also includes an amount of a non-surfactant additive such that, on diluting the suspension with a pharmaceutically acceptable diluent suitable for parenteral administration to a pharmaceutically acceptable concentration for parenteral administration, a suitable osmotic pressure of the diluted suspension results.

43. (New) The suspension of claim 38, wherein the thermoprotecting agent is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol, and mixtures thereof.

44. (New) The suspension of claim 38, wherein the one or more surface modifiers are natural phospholipids or synthetic phospholipids.

45. (New) The suspension of claim 44, wherein the natural phospholipid is an egg phospholipid or soy phospholipid.

46. (New) The suspension of claim 38, wherein the amount of the surface modifier provides a biologically active substance to surface modifier ratio of up to 5:1.

47. (New) The suspension of claim 38, wherein the amount of the surface modifier is in the range from about 0.2% w/w to about 5.0% w/w.

48. (New) The suspension of claim 38, wherein the composition also contains a pharmaceutical excipient suitable for ophthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble biologically active substance.

49. (New) The suspension of claim 38, wherein the active substance is an antifungal agent.

50. (New) The suspension of claim 49, wherein the antifungal agent is itraconazole.

51. (New) The suspension of claim 38, wherein the active substance is an immuno-suppressive drug.

52. (New) The suspension of claim 51, wherein the immuno-suppressive drug is a cyclosporin.

53. (New) The suspension of claim 38, wherein the active substance is a sterol.

54. (New) The suspension of claim 53, wherein the sterol is alfaxalone.

55. (New) A lyophilized or spray dried powder prepared from the suspension of claim 38.

56. (New) The suspension of claim 38, wherein the water-insoluble or poorly water-soluble biologically active substance is at a concentration suitable for either immediate release or sustained release delivery of the active substance by parenteral administration.

34

35 57. (New) The suspension of claim 56, wherein the parenteral administration is intramuscular, intravenous, or subcutaneous administration.

N.C. 58. (New) A method for preparing an aqueous suspension comprising particles of a water insoluble or poorly soluble biologically active substance, one or more surface modifiers, and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, the aqueous suspension having particle size stability during steam sterilization such that the increase in volume weighted mean particle size during steam sterilization is not more than about two-fold, the method comprising sealing in a vial under nitrogen atmosphere, a composition comprising water, particles of a water insoluble or poorly soluble biologically active substance, one or more surface modifiers, and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, and steam sterilizing the suspension in the vial.

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59. (New) The method of claim 58, wherein the one or more surface modifiers are natural phospholipids or synthetic phospholipids.

60. (New) The method of claim 58, wherein the ratio of the amount of the biologically active substance to the amount of the surface modifier is from 1:1 to 5:1.

61. (New) The method of claim 58, wherein the polyhydroxy thermoprotecting agent is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol, and mixtures thereof.

62. (New) An aqueous suspension prepared by the method of claim 58.